

Application No.: 09/806,842

Docket No.: 220002065000

REMARKS

Claims 16-39 are pending. Claims 16, 17 and 23-25 are amended. Claims 1-15, 18-20, 26 and 29-39 are canceled. No new matter has been added by way of these amendments nor is any further searching required of the Office. Support for the amendments is provided in the provisional application and throughout the specification as filed. Specific reference to passages relied upon for support are discussed in the Remarks below. Accordingly, entrance of these amendments and consideration of the remarks below is respectfully requested.

Examiner Change

Applicants acknowledge that Examiner Lyles is now handling the prosecution of this matter.

The Pending Claims Are Fully Supported By The Specification

Claims 16-28 were rejected under 35 U.S.C. § 112, first paragraph, as allegedly containing subject matter that was not adequately described such that one of ordinary skill in the art could reasonably conclude that Applicants were in possession of the invention at the time the application was filed. Specifically, the Office has alleged that the application and its priority documents do not support a method for identifying an inhibitor of NACP/ α -synuclein aggregation in the presence of a metal-in catalyzed oxidative condition. Applicants respectfully disagree.

The provisional application provides written support for various metals that promote NACP/ α -synuclein aggregation. For example, the provisional application discloses that ferric ions stimulate NACP/ α -synuclein aggregation on page 22. The provisional application also discloses that iron-catalyzed oxidative reactions on page 22 and that aluminum salts also promote NACP/ α -synuclein aggregation on page 19. Accordingly, the Office's allegation that the scope of the pending claims encompasses new matter is in error. Nevertheless, solely to advance the prosecution of the present application, the pending claims have been amended to recite an assay which uses iron-catalyzed oxidation to promote NACP/ α -synuclein aggregation. Regarding claims 24-26, these claims have been amended to clarify the nature of the iron used to catalyze the aggregation reaction.

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Explicit written support for this claim language is provided on pages 22-23 and elsewhere in the provisional application.

Claims 17-20 were rejected under 35 U.S.C. § 112, first paragraph, for allegedly failing to comply with the written description requirement. Specifically, the Office rejected the recitation of the phrase "non-amyloidogenic protein." Applicants submit that the term is adequately supported by the present disclosure, claims 18-20 have been canceled and claim 17 has been amended to specify that β -synuclein is an example of an aggregation inhibitor.

Claims 16-28 were rejected under 35 U.S.C. § 112, first paragraph, for allegedly lacking enablement. Specifically, the Office alleged that the specification only provided sufficient guidance for one of ordinary skill in the art to practice the claimed invention using iron-catalyzed oxidative conditions. As discussed above, Applicants take the position that the entire genus of metal-ion catalyzed NACP/ α -synuclein aggregation is enabled. Nevertheless, solely to advance the prosecution of the pending application, the claims have been amended to recite iron-ion catalyzed oxidative conditions.

Claims 16-26 and 28 were rejected under 35 U.S.C. § 112, first paragraph, for an alleged lack of enablement. Specifically, the Office alleged that the claimed method was only enabled for use where a single source was used to prepare the first and second samples recited in claim 16. Applicants respectfully disagree.

While Applicants agree that it would be "best scientific practice" to use a single source for testing in both the control and experiment tubes, it is not essential to do so. The use of best scientific practices is not a requirement for an applicant to obtain U.S. patent protection. All that is required is that the application teaches one of ordinary skill in the art how to make and use the claimed invention without undue experimentation. Here, functionally equivalent samples of NACP/ α -synuclein can be used in the claimed assay. Applicants readily contemplate a situation where recombinant NACP/ α -synuclein obtained from one lot is used to test an inhibitor where the control lot is obtained from another source. So long as the two samples contain bona fide samples of NACP/ α -synuclein, the assay will function. Accordingly, it is not "essential" that the same source of NACP/ α -synuclein be used in the first and second samples.

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In view of the amendments and remarks provided above, Applicants respectfully request that the Office withdraw the present rejections made under 35 U.S.C. § 112, first paragraph.

The Pending Claims Are Definite

Claims 17-20 were rejected under 35 U.S.C. § 112, second paragraph, as allegedly being indefinite. Applicants have canceled claims 18-20. Claim 17 has been amended to specify that the "test compound" of claim 16 is β -synuclein. Substitution of the term "test compound" for "aggregation inhibitor" overcomes the present rejection.

The Provisional Application Supports The Use Of "Iron-Catalyzed Oxidative Conditions"

The Office has alleged that neither the provisional nor the PCT application, from which the present case claims priority, supports the use of "metal-ion catalyzed oxidative conditions." Applicants respectfully disagree. In addition to iron-catalyzed oxidative conditions, which are discussed, *inter alia* on page 22, the ability of aluminum salts is explicitly disclosed on page 19 of the provisional application. Nevertheless, solely to advance the prosecution of the present case, Applicants have amended the subject matter of the pending claims to recite the use of iron-catalyzed oxidative conditions in the claimed method. These conditions are more than adequately supported by the provisional application, as the Office repeatedly admits throughout the present Office Action. Accordingly, Applicants submit that the present application is entitled to claim the filing date of the provisional application, October 6, 1998, as its priority date. As such, the filing date of the provisional application is used to determine which of the prior art references discussed below are proper art references.

The Subject Matter Of The Pending Claims Is Novel

Claims 16-28 were rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by Hashimoto, *et al.*, *NeuroReport* 10:717-721 (1999). Applicants submit that this reference is not available as prior art against the pending claims because it was disclosed as part of the provisional application, specifically at pages 17-28. Because this reference was published after the priority date

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of the provisional application, it is not available as prior art. Accordingly, this rejection has been overcome and should be withdrawn.

Claims 16-20 were rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by *Jensen, et al.*, Biochem. J., 323:539-546 (1997) as evidence by *Harris, et al.* Experimental Neurology, 131(2): 193-202 (1995). "Invalidity for anticipation requires that all of the elements and limitations of the claim are found within a single prior art reference. ...There must be no difference between the claimed invention and the reference disclosure, as viewed by a person of ordinary skill in the field of the invention." See *Scripps Clinic & Research Foundation v. Genentech, Inc.*, 927 F.2d 1565 (Fed. Cir. 1991). The *Jensen, et al.* does not teach a metal-ion oxidative condition, nor does it teach an iron-ion catalyzed oxidative condition. Accordingly, this reference does not teach all the limitations of the claimed invention.

The Office looks to the teachings of *Harris, et al.* to ameliorate the deficiencies of *Hensen, et al.*, presumably under a theory of inherency, although the Office failed to articulate its theory in the Action. The Office alleged that the *Harris, et al.* reference teaches an oxidative state. Without commenting on the position taken by the Office, the *Harris, et al.* does not teach a metal-ion catalyzed oxidative condition. Thus, neither *Jensen, et al.* nor *Harris, et al.* anticipate the pending claims. Accordingly, the present rejection is traversed.

Claims 16, 21-22, 24-28 were rejected under 35 U.S.C. § 102(a) and (e) as allegedly being anticipated by *Wolozin, et al.*, U.S. Patent No. 6,780,971, filed on July 9, 2001 and issued on August 24, 2004. As discussed above, the present application is fully entitled to claim priority to the provisional application, filed on October 6, 1999. As such, the *Wolozin, et al.* patent is not available as prior art against the pending claims. Accordingly, this rejection is traversed.

The Pending Claims are Non-Obvious

Claims 16, 21-22, 24-28 were rejected under 35 U.S.C. § 103 as allegedly being obvious over *Biere, et al.* U.S. Patent 6,184,351, filed on September 24, 1999 and issued on February 6, 2001. The *Biere, et al.* reference, like the *Wolozin, et al.* reference, is not available as prior art against the pending claims. Accordingly, this rejection is traversed.

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Claims 21-23 were rejected under 35 U.S.C. § 103 as allegedly being obvious over Hashimoto, *et al.*, in view of Wolozin, *et al.*, and further in view of Narhi, *et al.*, JBC 274(14): 9843-9846 (1999). As discussed above, neither the Hashimoto, *et al.* nor the Wolozin, *et al.* references are available as prior art against the pending claims. Thus, only the Narhi, *et al.* reference need be addressed in this response.

For the Narhi, *et al.* reference to render the pending claims obvious, its teachings must teach or suggest all the limitations of the claimed invention, provide a reasonable expectation of success, and provide a motivation to modify the reference to achieve the claimed invention. Narhi, *et al.* may suggest the high throughput screening of compounds that block α -synuclein, but without the teachings provided in the other references, Narhi, *et al.* does not support a prima facie case of obviousness. Accordingly, the present rejection has been traversed and should be withdrawn.

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CONCLUSION

In view of the above, each of the presently pending claims in this application is believed to be in immediate condition for allowance. Accordingly, the Examiner is respectfully requested to withdraw the outstanding rejection of the claims and to pass this application to issue. If it is determined that a telephone conference would expedite the prosecution of this application, the Examiner is invited to telephone the undersigned at the number given below.

In the event the U.S. Patent and Trademark office determines that an extension and/or other relief is required, applicants petition for any required relief including extensions of time and authorize the Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to Deposit Account No. 03-1952 referencing docket no. 22000-2065000. However, the Commissioner is not authorized to charge the cost of the issue fee to the Deposit Account.

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Respectfully submitted,

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